

Rejection Under 35 USC 103

Claims 1,2,5-24 and 29-51 have been rejected by this examiner under 35 USC Section 103(a) as being obvious in view of *Sweeney* (U.S. Patent No. 5,599,318) and *Bevilacqua*, (U.S. Patent No.5, 509,907).

However, we resubmit to the examiner that those claims were substantially disclosed in earlier patents such as (U.S. Patent No. 4,820,277; 4,664,259; 5,188,611). Therefore this application does not seek approval to of 5-24 and 29-51 for the protrusion of each side of the inner sheath as the locking mechanism but as a cannula guide. This cannula guide (keeper shelf 13 acting as a secondary holding stage) is used to secure the cannula in place while the actually permanent locking mechanism is in the base of the sheath. See figure 3. Examiner continues to state: "Claims 20,21 40-432 and 50, needle (14) is attached to a well (26) from which at least four equally spaced wings protrude, and it would have been obvious to one of ordinary skill in the art a time the invention was made to provide at least a portion of said well within the base." The examiner is correct in this opinion if the reference were to the primary locking mechanism. However, this patent application uses its described protrusions inside the sheath and exterior to the base as a keeper or guide not as a primary locking mechanism. The protrusions have a different not thought of before function. It was not obvious in the design of the prior art that the wings enclosed described in the prior patents would be significant as a guide for the strength of a permanent locking mechanism elsewhere. The two "guide lugs" or "keeper shelf" are an *integral geometrical* necessity to the audible permanent locking mechanism as described below in this patent in claims 3, 4, 20, 21, 27, 28, 40-42,

With respect to Applicant's independent claims 3,4, 27 and 28 Applicant respectfully submits that the subject matter claimed therein patentable and distinguishes over *Sweeney*. Specifically, Applicant's independent claim 20,21,40-42 recites two protrusions with a specific trade secret angle (cork drill design imbedded in the hinge covered by molded plastic) which contributes to the permanent locking mechanism strength in the base of the sheath shown in figure 3.

Applicant's respectfully submits all of the above claims for reconsideration with the following rewrite. Look at the locking mechanism by reference to Fig 1, with the guard in the open position, because the elements of the locking mechanism are more readily visible. Base 2 of the device of the present invention includes two side lugs 3 and one opposing conclave lug 4. Opposing lug 4 is positioned opposite hinge connection 17 such that opposing lug 4 will snap snugly into the side opening of the longitudinal member 6. Side lugs 3 are positioned on the two sides of the base 2. Longitudinal member 6 includes a horseshoe-shaped smooth protrusion 16 at the lower end of the side opening of longitudinal member 6. Preferably, on both sides of the horseshoe-shaped protrusion 16 are small tabs 7 that are fabricated to fit snugly in the two gaps defined by each of the side lugs 3 with the opposing lug 4. Additionally, as illustrated in Figure 1, side lugs 3 are shaped such that they also function as a pair of snap catches catching the horseshoe-shaped protrusion 16 to hold longitudinal member 6 in a snap lock position. It should be noted that when the snap lock lugs engage, they are permanently locked. Only fixed focus and extremely deliberate pressure with a very fine steel object will disengage the base lug lock described in this patent. This base lug locking mechanism is the permanent locking design aided by the cannula being in the guided position elongated above held in place by the guiding side protrusion in the sheath? The keeper shelves are positioned so that it is interposed between the opening in longitudinal member 6 and a needle or cannula at 5.

In the devices described in US Patent 5,913,846 and 5,746,726 this examiner acknowledges the use of a hinge technology, which permits the protective device to be replaced after use with a single-handed action. Indeed there are several patents that have this technology as it base for opening and closing the sheath to protect the sharp. However, none have defined the hinge, as an absolutely safe was to append the sheath to the cannula stand until this present invention. Focus on the US Patent 5,913,846 and 5,746,726 drawings and you will notice two prongs that eject for it to be pressed into the base of the cannula stand allowing it to rotate tongue and groove like during it's operation to open and shut. This design has proved to be inherently dangerous in that it comes apart inadvertently with just the right torsional pressure or inadvertent pressure during an emergency. The US Patent 48,820,277 also uses a butterfly type device wherein the cover or sheath is divided into two halves that separate if torked in the wrong way. The hinge technology that this inventor submits is a single molded hinge that does not separate and is formed internally as a wine bottle cork remover molded over with molded plastic to allow for many hundreds of openings but the cover or sheath will never become separated from the needle base. This is an extremely important feature that many healthcare providers are preferring due to the added assurance that the product with never become separated and leave them with no protection. In all of the other devices approved for patents thus far in this category there is inherent danger in accidental breakage that is commonplace where they are use today. The force required to lock the mechanism during this rotational operation can and has lead to undesirable accidental breakages and separations that defeats the purpose of the invention for an "engineered guard" protective safety device.

Applicant respectfully submits that the *prima facie* case of obviousness cannot be made in this case. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP 2142).

It is an established legal doctrine that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not in applicant's disclosure. *In re Vaek*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Neither *Sweeney*, or Szabo or any other cited prior art, nor the knowledge generally available to one of ordinary skill in the art, suggest or motivate to modify the references to make an engineered guard that functions as one unit having the protrusion guides geometrically necessary to assist in the permanent locking mechanism functioning as a one-handed secure audible clicked device manufactured so that no parts ever separate from unexpected pressures or pulling.

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Applicant respectfully points out that the Examiner did not provide such a line of reasoning as to why the artisan would have found the invention claimed in Applicant's independent claim 3 through 35 to have been obvious in light of the *Sweeney* or any other prior art reference.

Moreover, neither *Sweeney*, nor any other cited prior art, teach or suggest all the claim limitations. As discussed in detail above, Applicant's independent claim 3,4,15 through 25 is not taught or suggested in *Sweeney* in that *Sweeney* does not teach or suggest an integral geometry or a one piece permanent locking mechanism which connects the securing body housing 8 to the cannula holder base.

Therefore this Applicant respectfully submits the restatement of the objected to claims and ask for patentable reconsideration to the modified and further explained claims 5 through 25.

CONCLUSION

Reconsideration and further examination is respectfully requested.

Applicant has made a diligent effort to place the claims in condition for modified description and allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Yovette Mumford, Applicant Attorney at (781) 721-0509 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

Yovette Mumford

Date: 4/9/02